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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,444	02/02/2000	Yumin Tao	1109	6243

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/496,444

Applicant(s)

TAO ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-18, 22-25, 27-53 and 64-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22, 65, 70 and 75 is/are allowed.
- 6) ☒ Claim(s) 2-18, 23-25, 27-53, 64, 66-69 and 71-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on December 18, 2001, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/496444 is acceptable and a CPA has been established. An action on the CPA follows.

Claim 64 has been newly amended.

Claims 65-75 have been newly added.

Claims 2-18, 22-25, 27-53, and 64-75 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The rejection of claim 22 under 35 U.S.C. 112, first paragraph, for written description, is withdrawn in light of the fact that claim 22 is drawn to a ribonucleic acid encoding a protein of SEQ ID NO:2, which is adequately described.

Claims 2-18 remain rejected, claims 23-25 and 27-53 are rejected, newly amended claim 64 is rejected, and newly added claims 66-69 and 71-74 are rejected, under 35 U.S.C. 112, first paragraph, for written description, for the reasons of record set forth in the previous office actions.

Applicant argues that an adequate written description of a claimed genus can be made via structure, and that a genus of DNAs may be defined by the recitation of a representative number of DNAs. Applicant argues that the requirement of adequate written description has been met because the claims recite a predictable structure having a high % sequence identity (80%, 90% or

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95%). Applicant also argues that the written description requirement may be satisfied by a recitation of functional characteristics in the description, provided there is a correlation between the function and the structure of the claimed invention (*Eli Lilly* at 1568). Applicant refers to Example 14 of the Revised Interim Written Description Guidelines for support. Applicant points out that all the claims have been drafted with the functional limitation that the nucleotide sequence claimed require cyclin E activity or are capable of modulating the level of cyclin E protein in a cell.

Applicant's arguments have been fully considered but are not persuasive.

The Examiner acknowledges the recitation of functional limitations in the claims but maintains that the specification does not disclose a representative number of DNAs. The specification discloses only one sequence encoding a protein with cyclin E activity, the nucleotide sequence of SEQ ID NO:1 encoding the amino acid sequence of SEQ ID NO:2. The Examiner maintains that the mere recitation of sequences having varying degrees of sequence identity to SEQ ID NO:1 does not meet the written description requirement. Regarding Example 14 of the Revised Interim Written Description Guidelines, which suggests that functional sequence variants at least 95% identical to a disclosed sequence are adequately described when there is an actual reduction to practice of a single disclosed species, the Examiner points out that Example 14 is based on the assumption that procedures for making the sequence variants that have 95% identity and retain activity are conventional in the art. The Examiner maintains that procedures for making sequence variants that retain cyclin E activity are not conventional in the art. The Examiner also maintains that the specification does not disclose how the structure of the claimed invention is correlated with cyclin E activity.

Accordingly, Applicant's arguments are not persuasive.

The rejection of claim 22 under 35 U.S.C. 112, first paragraph, for enablement, is withdrawn in light of the fact that claim 22 is drawn to a ribonucleic acid encoding a protein of SEQ ID NO:2, which is enabled.

Claims 2-18, 23-25, and 27-53 remain rejected, newly added claim 64 is rejected, and newly added claims 66-69 and 71-74 are rejected, under 35 U.S.C. 112, first paragraph, for enablement, for the reasons of record set forth in the previous office actions.

Applicant argues that in addition to the full length polynucleotides of the present invention the specification provides guidance on modifications and variants as well as methods to identify compositions and assays to determine their functionality. Applicant argues that the requirement for assaying does not mean the invention is not enabled, and that testing to determine functionality is routine. Applicant further points out that using only the degeneracy of the genetic code one could produce a polynucleotide of only approximately less than 80% sequence identity to the sequences claimed without changing the amino acid sequence of the encoded polypeptide.

Applicant's arguments have been fully considered but are not persuasive.

The Examiner maintains that the specification does not disclose modifications or variants of SEQ ID NO:1. The Examiner also maintains that the disclosure of methods to identify compositions and assays to determine their functionality does not enable the invention in the absence of the disclosure of the structural features of the claimed sequences that are critical to the claimed functions. Additionally, the Examiner maintains that the rejected claims are not

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drawn to degenerate polynucleotide sequences that encode polypeptides of a single amino acid sequence.

Accordingly, Applicant's arguments are not persuasive.

***Claim Rejections - 35 USC § 101***

The rejection of claims 2-15 and 22 under 35 U.S.C. 101 as not being supported by a specific and substantial utility is withdrawn in light of the assertion that function and utility are demonstrated on page 2 of the 1.132 Declaration submitted June 28, 2001, where it is disclosed that the putative CycE gene of the instant invention complements the G1-cyclin deficient yeast, which functionally verifies that this gene is a G1 cyclin.

Claims 16-18 remain rejected under 35 U.S.C. 101 as not being supported by a specific and substantial utility.

Applicant argues that the rejection should be withdrawn in light of the disclosure that the putative CycE gene of the instant invention complements the G1-cyclin deficient yeast, which functionally verifies that this gene is a G1 cyclin.

Applicant's argument has been fully considered but is not persuasive.

Claims 16-18 are drawn to transgenic plants and seed comprising the isolated nucleic acid of the instant invention. Since nontransformed plants already possess endogenous cyclin E genes, the claimed invention is not supported by a specific and substantial utility in the absence of evidence that the claimed transgenic plants and seed have some specific and substantial utility relative to nontransformed plants.

Accordingly, Applicant's arguments are not persuasive.

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***Remarks***

Claims 2-18, 23-25, 27-53, and 64, 66-69 and 71-74 are rejected.

Claims 22, 65, 70 and 75 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
February 19, 2002

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800

*E. F. McElwain*